IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC., a New Jersey corporation; and QUEEN'S UNIVERSITY AT KINGSTON, a Canadian academic organization,	Civil Action No. 04-12703-NMG
Plaintiffs,	
v.	**Oral Argument Requested**
NEW ENGLAND COMPOUNDING PHARMACY, INC., a Massachusetts corporation,	
Defendant.	

PLAINTIFFS' MEMORANDUM OF LAW IN SUPPORT OF MOTION TO COMPEL ENTRY AND INSPECTION OF DEFENDANT'S PREMISES AND OPERATIONS

Plaintiffs DUSA Pharmaceuticals, Inc. ("DUSA") and Queen's University at Kingston ("Queen's University") (collectively "Plaintiffs") hereby submit this memorandum in support of their motion to compel Defendant New England Compounding Pharmacy, Inc. ("Defendant") to permit access to Plaintiffs and their agents for entry and inspection of Defendants' premises and operations believed to be located at 697 Waverly Street, Framingham, Massachusetts 01702.

I. INTRODUCTION

In response to Plaintiffs' complaint asserting patent infringement, Defendant alleges a five count counterclaim that make the quality and source of its ALA-containing product a central issue in this case. Each of the five causes of action asserted by Defendant as a counterclaim to the above-captioned action is grounded in the allegation that "DUSA made false and/or deceptive representations to customers, such as false and/or misleading remarks disparaging the

quality and source of NECP's compounds comprising ALA solution." Defendant's Counterclaims, at ¶ 22 (emphasis added); *see also* ¶¶ 14, 18, 23, 26, 30, 31. The manner and conditions under which Defendant's ALA-containing product is made, as well as the procedural safeguards associated with the storage, labeling, packaging and record keeping system are thus highly relevant and an appropriate area for discovery. In accordance with Fed. R. Civ. P. 34, therefore, Plaintiffs served a request to enter and inspect Defendant's premises.

Defendant has refused to permit this inspection. In an effort to reach a resolution, Plaintiffs' counsel has engaged in more than three weeks of negotiation, which included the exchange of six lengthy and detailed letters, two telephone conferences (not including a call that Defendant's counsel did not return), and two e-mail exchanges. Plaintiffs also assented to compromise on five of the seven conditions originally proffered by Defendant. Despite these efforts, Plaintiffs find themselves before this Court because Defendant refuses to consent to an entry unless Plaintiffs agree to several conditions that will necessarily preclude the discovery of relevant evidence. Moreover, Defendant has belatedly asserted an additional condition – one that is wholly irrelevant to an entry and inspection of Defendants' premises – to further delay and obstruct discovery.

In view of Defendant's refusal, Plaintiffs have no choice but to seek to compel an entry and inspection of all relevant areas of Defendant's facility in accordance with the proposed Order attached hereto.

II. FACTUAL BACKGROUND

Plaintiffs brought a patent infringement suit against Defendant on December 27, 2004. Defendant responded with its Answer, Counterclaim and Jury Demand ("Defendant's Counterclaims"), which among other things asserted counterclaims grounded in the allegation

that Plaintiffs made false and/or misleading remarks disparaging the quality and source of Defendant's ALA-containing products. *See* Defendant's Counterclaims, at ¶¶ 14, 18, 22, 23, 26, 30, 31. Thus, it is the Defendant's own counterclaims that put the quality and source of Defendant's product at issue, and render the entry and inspection of Defendant's facility essential to the discovery of relevant information. Importantly, there is no claim that makes relevant the manufacturing practices or quality of Plaintiffs' products.

On July 15, 2005, Plaintiffs served Plaintiffs' Request for Entry Upon Land Directed to New England Compounding Pharmacy, Inc. ("Plaintiffs' Request for Entry"), seeking to enter the Defendant's premises on Tuesday, August 16, 2005. *See* Exhibit A (Plaintiffs' Request for Entry).

A detailed description of the negotiations between the parties, and Plaintiffs' efforts to resolve this dispute in good faith are set forth in the Affidavit of Valerie Brand Pipano, Esq., attached hereto as Exhibit B.

III. ARGUMENT

Defendant demands that: (1) the inspection be limited only to the "laboratory" area in which the ALA-containing product is compounded; and (2) that certain containers and cabinets within the laboratory area (an area Defendant concedes is relevant) would be excluded from inspection. Belatedly, Defendant has also asserted a "tit-for-tat" condition that Plaintiffs submit their facility to an entry and inspection by Defendant – a demand that is utterly irrelevant to the issues raised by Plaintiffs' infringement claims or Defendant's counterclaims.

Each of these demands should be rejected pursuant to the broad scope of Rules 26(b)(1), allowing parties to "obtain discovery regarding any matter . . . that is relevant to the claim or defense of any party." Fed. R. Civ. P. 26(b)(1); *see also* Fed. R. Civ. P. 34(a)(2) ("entry upon

designated land or property in the possession or control of the party upon whom the request is served for the purpose of inspection and measuring, surveying, photographing, testing, or sampling the property or any designated object or operation thereon . . . ").

A. Inspection Should Not Be Limited To Merely The Area Where The ALA-Containing Product Is Compounded.

Defendant demands that the inspection be limited to the "laboratory" area in which it claims that the ALA-containing product is compounded. *See* Exhibit B, Affidavit of Valerie Brand Pipano, at ¶¶ 10, 19, 20; Exhibit 5 thereto (Defendant's August 18, 2005 correspondence). However, the quality and source of a drug can not be assured without an examination of the entire premises in which it is manufactured,[1] including an assessment of the methods used in, and the controls used for, the product's manufacture, processing, packing and/or storage. *See* Exhibit C (Affidavit of David L. Chesney), at ¶¶ 8-13.

An examination of these practices and conditions is crucial to determining the quality and source of a drug product. *Id.*, ¶¶ 10-11. The reason for this is clear. The risk of contamination of a drug product, or the existence of factors that may contribute to the failure of a drug product to meet its specifications and acceptance criteria may occur prior to, during or after the manufacturing process – and not simply in the compounding "laboratory" as Defendant suggests. *Id.*, ¶ 12. The strict control of all aspects of the processes, procedures and conditions – extending beyond simply the area of manufacturing – are routinely employed as the means of assuring the safety, identity, strength, quality and purity characteristics of drug products. *Id.*, ¶¶

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[1] In the course of negotiation, Defendant attempted to draw a distinction between words like "manufacture" and "fabricate" and the purported compounding process performed by NECP to manufacture their ALA-containing product. In the context of an infringement action, and specifically for the purposes of discovery in the above-captioned matter, it is inappropriate to draw this distinction.

11-12. Indeed, these are the best available methods to insure that a product conforms to the standards that patients, physicians and hospitals expect of a drug sold in this country. *Id.*, ¶ 11. Therefore, limiting inspection to the area in which ALA-containing product is manufactured is wholly insufficient and will preclude the discovery of relevant information.

An assessment must properly include all areas of the premises in which processes relating to the quality and source of the product occur. Such areas include those places for the receipt, sampling and testing of raw materials, containers, closures, packaging and labeling materials; the use and maintenance of equipment and utilities; and the creation and use of pertinent records, files, papers and other materials generated in connection with manufacturing, packaging, testing and distribution of the drug product. *Id.*, ¶¶ 12-13.

B. Plaintiffs Must Be Permitted To Inspect Certain Containers And Cabinets Within The Laboratory Area – An Area Defendant Concedes Is Relevant.

Not only does Defendant seek to limit the inspection to its "laboratory," Defendant also seeks to keep Plaintiffs from inspecting certain containers and cabinets contained within the "laboratory" where its ALA-containing product is compounded. *See* Exhibit B, Affidavit of Valerie Brand Pipano, at ¶¶ 10, 19, 20; Exhibit 5 thereto (Defendant's August 18, 2005 correspondence).

This condition is indefensible. Defendant has already conceded the relevancy of an inspection of the compounding laboratory. Indeed, it is the only area in which Defendant has voluntarily agreed to allow inspection. *Id.* In a matter in which Defendant has placed at issue the safety, identity, strength, quality and purity characteristics of its ALA-containing product, Plaintiffs are entitled to know, for example, if these cabinets and/or containers hold materials that

might cause cross-contamination or are otherwise not permissible in a manufacturing area.[2] *See* Exhibit C (Affidavit of David L. Chesney), at ¶¶ 12-13.

C. Defendant Should Not Be Permitted To Delay The Inspection With Untimely And Irrelevant Demands.

All timely objections to the entry and inspection were required to be served on Plaintiffs by August 15, 2005. *See* Fed. R. Civ. P. 34(b) (allowing a thirty day period for serving objections to a request for entry upon land). On August 26 – eleven days after this deadline, and as part of the parties' second 'meet and confer' conference – Defendant raised for the first time that the inspection would not go forward unless Plaintiffs agreed to an inspection by Defendant of the DUSA manufacturing facility. *See* Exhibit B (Affidavit of Valerie Brand Pipano), at ¶¶ 22, 24; Exhibit 7 thereto (Defendant's August 26, 2005 correspondence).

The Court should not consider this argument.

Case law is clear that the failure to raise timely objections to discovery requests constitutes a waiver of any such objections. *See, e.g., Marx v. Kelly, Hart & Hallman, PC*, 929 F.2d 8, 12 (1st Cir. 1991); *Kooker v. Susan Marie II, Inc.*, No. Civ. A. 98-10282, 1998 WL 34061513, *1 (D. Mass. 1998); *Willard v. Constellation Fishing Corp.*, 136 F.R.D. 28, 31 (D. Mass. 1991); *see also* Fed. R. Civ. P. 34(b). As recognized in *Marx*, an objection subsequent to the allowed thirty day period gives "the appearance of a further stalling tactic rather than a good

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[2] Defendant also represented in the August 26 letter that Plaintiffs had agreed as part of the second 'meet and confer' conversation that, based solely on Defendant's representation that there is nothing relevant contained therein, they would not seek to inspect the containers and cabinets within the compounding laboratory. This is not the case. Plaintiffs agreed only that if Defendant provided a sworn affidavit as to the contents of those containers and cabinets, and the expert confirmed that such contents could not cross-contaminate the ALA-containing product or were otherwise not relevant, Plaintiffs would consider withdrawing its demand to inspect these containers and cabinets. Moreover, any concerns that the inspection of these cabinets and containers will reveal commercially sensitive information are obviated by the protective order already in place.

faith effort to comply with the Rules. . . ." *Marx*, 929 F.2d at 12. Defendant's belated assertion of this new condition is similarly an attempt to delay and subvert Plaintiffs' proper inspection of Defendant's premises.

In this regard, it is worth noting that Defendant has not issued a notice to enter upon Plaintiffs' land, and so Plaintiffs cannot raise specific objections to the exact inspection that might be proposed. That is perhaps part of Defendant's tactics. Defendant may eventually issue such a notice, which will be objectionable on specific grounds, allowing Defendant to seek to further delay inspection of its premises while dragging out argument concerning its proposed inspection of Plaintiffs' facility – the inspection of which cannot lead to the discovery of admissible evidence regardless of the scope of entry.

Even if Defendant had timely raised this condition, it should still be rejected by this Court. The quality and source of the Defendant's product was placed at issue by Defendant's counterclaims, all of which are grounded in the claim that Plaintiffs made false and/or misleading remarks disparaging the quality and source of Defendant's ALA-containing product.

Conversely, Defendant's hypothetical inspection of DUSA's premises could not lead to the discovery of admissible evidence because the quality and source of Plaintiffs' product is not at issue. There has been no allegation *by either side* regarding the characteristics of Plaintiffs' ALA-containing product. There cannot be. Plaintiffs' products and premises have been subjected to the rigors of an FDA inspection. Defendant's product and premises have not. Perhaps in recognition of this fact, Defendant has not sought to properly notice an entry upon land, but only belatedly raises this condition in an attempt to prevent the inspect of Defendant's facility.

Accordingly, because this condition is untimely, and cannot lead to the discovery of admissible evidence in any event, it is not properly considered by the Court.

IV. CONCLUSION

For the reasons set forth above, Plaintiffs respectfully request that this Court enter an Order compelling Defendant to permit an entry and inspection of its facility and operations within seven (7) days of the date of the Order. Such inspection shall include all relevant areas of Defendant's premises likely to lead to the discovery of admissible evidence, shall not be limited to Defendant's compounding "laboratory," and shall include the inspection of all containers and cabinets contained therein. A proposed order is submitted herewith.

Respectfully submitted,

DUSA PHARMACEUTICALS, INC. and
QUEEN'S UNIVERSITY AT KINGSTON

By their attorneys,

/s/ Mona M. Patel
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William J. McNichol, Jr. (*pro hac vice*)
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Dated: September 8, 2005

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC., a New Jersey corporation; and QUEEN'S UNIVERSITY AT KINGSTON, a Canadian academic organization,	:	Civil Action No. 04-12703-NMG
Plaintiffs,	:	
v.	:	[JURY TRIAL DEMANDED]
NEW ENGLAND COMPOUNDING PHARMACY, INC., a Massachusetts corporation,	:	
Defendant.	:	

PLAINTIFFS' REQUEST FOR ENTRY UPON LAND
DIRECTED TO NEW ENGLAND COMPOUNDING PHARMACY, INC.

PLEASE TAKE NOTICE THAT pursuant to Fed. R. Civ. P. 34, Plaintiffs DUSA Pharmaceuticals, Inc. ("DUSA") and Queen's University at Kingston ("Queen's University") (collectively "Plaintiffs") hereby request that Defendant New England Compounding Pharmacy, Inc. ("Defendant") permit access to Plaintiffs and their agents for entry (the "Requests") upon the land described herein (the "Premises") in accordance with the instructions set forth below. If Defendant fails to comply with these Requests, Plaintiffs reserve all rights and remedies available to it including the right to compel access to the Premises and to seek sanctions, including but not limited to, limitation of the evidence which may be presented at the hearing as scheduled in the above referenced case.

You are required to supplement your response to these Requests in accordance with Fed. R. Civ. P. 26.

DEFINITIONS

1. "Date" means the exact day, month and year.

2. "Premises" means the principal place of business of Defendant in which Defendants manufacture, fabricate, compound, produce and/or store of the aminolevulinic acid solution at issue in the above-captioned litigation and any components thereto, and in which Defendants keep records relating to the manufacture, fabrication, compounding, production and/or storage of the aminolevulinic acid solution. Plaintiffs believe the Premises to be located at 25 Upton Drive, Wilmington, MA 01887.

3. "Inspectors" means Plaintiffs, Plaintiffs' counsel, any outside inspector retained by Plaintiffs, and/or any photographer(s) retained by Plaintiffs.

4. "Defendant," "you" or "your" means Defendant New England Compounding Pharmacy, Inc., its officers, agents, servants, employees, attorneys, those persons in concert with them, and/or any other person or party in possession or control of the Premises.

5. Any reference to a person or corporation in these Requests includes agents, employees, officers, attorneys or anyone acting on behalf of that person or corporation.

INSTRUCTIONS

Pursuant to Fed. R. Civ. P. 34, Defendant shall respond to the Requests, separately and in writing, on or before August 15, 2005. If Defendant, by its counsel, wants to suggest an alternative date for consideration by Plaintiffs, it should do so in writing to counsel for Plaintiffs by no later than August 15, 2005. Absent response to the contrary, Plaintiffs shall make arrangements for inspection on the date set forth below. Plaintiffs request that the inspections commence at 8:30 a.m. on the date specified, and continue for a reasonable time thereafter until

complete. A representative of Defendant or its counsel must be on site to provide access to the Property.

REQUESTS

Pursuant to Fed. R. Civ. P. 26 and 34, and all applicable Local Rules, Plaintiffs propound the following Requests to permit the inspection and photography (still and video) of the Premises, on the Date and in the manner indicated:

1. Plaintiffs request entry for the Inspectors at the Premises on **Tuesday, August 16, 2005** at **8:30 a.m.**, and continuing until such inspection is complete.

2. Plaintiffs request inspection and photographing/videotaping by Inspectors of the Premises. Specifically, the inspection and photography/videotaping shall include the areas and activities related to the manufacture, fabrication, compounding, production and/or storage of the aminolevulinic acid solution at issue in the above-captioned litigation and any components thereto. The inspection and photographing/videotaping shall also include the area in which records are kept relating to the manufacture, fabrication, compounding, production and/or storage of the aminolevulinic acid solution.

3. The Inspectors shall be permitted to conduct reasonable measuring, testing and/or sampling of the areas and activities related to the manufacture, fabrication, compounding, production and/or storage of the aminolevulinic acid solution and records thereto at issue in the

above-captioned litigation and any components thereto.

DUSA PHARMACEUTICALS, INC. and
QUEEN'S UNIVERSITY AT KINGSTON.

By their attorneys,

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10 St. James Avenue
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(617) 523-6850 (fax)

William J. McNichol, Jr.
Maryellen Feehery
Valerie Brand Pipano
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dated: July 15, 2005

CERTIFICATE OF SERVICE

I, Mona M. Patel, hereby certify that on this 15th day of July, 2005, I caused the within Plaintiffs' Request for Entry Upon Land Directed to New England Compounding Pharmacy, Inc. to be served upon the defendant in this action by causing a copy thereof to be delivered by hand to defendant's counsel of record, Daniel M. Rabinovitz, Menard, Murphy & Walsh LLP, 60 State Street, 34th Floor, Boston, Massachusetts 02109.

Mona M. Patel

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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC., a New Jersey corporation; and QUEEN'S UNIVERSITY AT KINGSTON, a Canadian academic organization,	:	Civil Action No. 04-12703-NMG
Plaintiffs,	:	
v.	:	
NEW ENGLAND COMPOUNDING PHARMACY, INC., a Massachusetts corporation,	:	
Defendant.	:	

AFFIDAVIT OF VALERIE BRAND PIPANO, ESQUIRE

I, Valerie Brand Pipano, Esq., attest and state that I attempted in good faith to resolve this discovery dispute with Defendant's attorney by letter, e-mail and telephone, but to no avail. In support thereof, I hereby state as follows:

1. I am an associate with the law firm of Reed Smith LLP, 2500 One Liberty Place, 1650 Market Street, Philadelphia, PA 19103, and a member of the bar in good standing in the Commonwealth of Pennsylvania and the United States District Court for the Eastern District of Pennsylvania.

2. I am an attorney of record for Plaintiffs DUSA Pharmaceuticals, Inc. ("DUSA") and Queen's University at Kingston ("Queen's University") (collectively "Plaintiffs"), and have been admitted pursuant to Local Rule 83.5.3(b) to appear pro hac vice in the above-captioned matter.

3. On July 15, 2005, Plaintiffs served Plaintiffs' Request for Entry Upon Land Directed to New England Compounding Pharmacy, Inc. ("Plaintiffs' Request for Entry"), seeking to enter the Defendant's facility on Tuesday, August 16, 2005.

4. On Friday, August 12, 2005, Plaintiffs received a letter from Defendant's counsel indicating that Defendant objected to the Entry on the grounds that it would not lead to the discovery of relevant information, and because a review of certain documents housed at Defendant's facility might implicate HIPAA concerns. Defendant also suggested that it would allow the Entry should Plaintiffs articulate the reason an entry and inspection would lead to the discovery of relevant information. **Exhibit 1**, Defendant's August 12, 2005 correspondence.

5. I responded, also on August 12, setting forth the reasons that the inspection of Defendant's premises is necessary to defend against the allegations asserted in NECP's counterclaims. I also explained that because the Entry is an inspection of Defendant's premises, and not a review of documents, patient privacy would not be an issue.[1] **Exhibit 2**, Plaintiffs' August 12, 2005 correspondence.

6. I further requested that, in order to accommodate travel concerns, Defendant advise us by noon on Monday, August 15, 2005 whether Defendant intended to allow the entry and inspection scheduled for the next day. Id.

7. Having not heard from Defendant by the requested time on August 15, I left a telephone message for Defendant, sent a letter inquiring as to whether Defendant

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[1] Plaintiffs further indicated that, in the context of documents produced pursuant to discovery requests, Defendants were amendable to protecting patient-sensitive information with appropriate redactions. **Exhibit 3**, Plaintiffs' August 12, 2005 correspondence.

would permit the entry, and seeking to 'meet and confer' about conditions under which an entry would be permitted. **Exhibit 3**, Plaintiffs' August 15, 2005 correspondence.

8. Defendant's counsel responded via email that Defendant would not permit the entry to go forward on the scheduled date of August 16, but suggested that a resolution was possible if counsel had additional time to discuss the matter with his client. **Exhibit 4,** August 15, 2005 email correspondence.

9. The parties agreed to meet and confer at 2 pm on August 18, 2005. Id.

10. On August 18, 2005, Defendant's counsel provided a letter suggesting seven conditions under which they might permit the entry to go forward. **Exhibit 5**, Defendant's August 18, 2005 correspondence. Plaintiffs' positions with respect to each of these conditions was discussed as part of the August 18 telephone conference, and Defendant's counsel asked that I place each of Plaintiffs' positions in writing.

11. The parties agreed that Defendant would consider Plaintiffs' position with respect to each condition, and inform Plaintiffs by 9 am on Friday, August 26, 2005 whether the entry and inspection would go forward without intervention from the Court.

12. On August 19, 2005, I provided the requested letter setting forth Plaintiffs' position with respect to each of the seven conditions proffered by Defendant, as reiterated from the 'met and confer' conversation the day before. **Exhibit 6**, Plaintiffs' August 19, 2005 correspondence.

13. Plaintiffs assented to Defendant's request to hold the entry on a date convenient for Defendant, and after business hours so as not to impede Defendant's business activity. Id.

14. Plaintiffs agreed that their representatives would not photograph or videotape Defendant's employees. Id.

15. Plaintiffs assuaged Defendant's purported HIPAA concerns by reiterating that it would not examine the contents of documents at the time of entry and inspection (as offered in the August 12 correspondence). Id.

16. Plaintiffs also agreed with Defendant that the parties should comply with the terms of entry and inspection as modified by the parties' agreement, and that the parties have the right to terminate the inspection and seek assistance from the Court should a party exceed the scope of the agreed inspection. Id.

17. Defendant had set forth a condition that Plaintiffs' inspection team could only consist of one company representative, one attorney, one photographer and one videographer. Plaintiffs' August 19 letter set forth the reasons that, along with the photographer and videographer, they would require the presence of two attorneys (one from the offices of lead counsel and one local counsel) and an expert on good manufacturing practices for drug products. Id.

18. As a compromise, Plaintiffs agreed not to bring a company representative to the entry and inspection. Id.

19. Plaintiffs also explained that they would be unable to concede to Defendant's remaining two conditions: that the inspection be limited only to the "laboratory" area in which the ALA-containing product is compounding, and that certain containers and cabinets within the laboratory area would be excluded from inspection. Id.

20. Plaintiffs indicated that they could not agree to these conditions. Id. Limiting the inspection in this manner would prevent a complete assessment of Defendant's manufacturing practices and therefore, the safety, identity, strength, quality and purity characteristics of its ALA-containing product. Id.

21. Having not heard from Defendant by the 9 am deadline on August 26, 2005, I contacted Defendant's counsel by telephone. At that time, Defendant's counsel offered conflicting and nonsensical excuses as to the reasons he did not yet have an answer from his client as to whether the entry could go forward.[2]

22. Defendant's counsel also proffered a new and untimely condition that in order for the entry and inspection to go forward, the DUSA Plaintiff's would have to submit to an inspection by Defendant.

23. Defendant's counsel further stated that Plaintiffs should expect a letter setting forth Defendant's position with respect to the entry and inspection.

24. When it arrived, Defendant's August 26 letter made clear that the parties would not be able to resolve the issues of whether the inspection would be limited only to the "laboratory" area in which the ALA-containing product is compounded, and whether Plaintiffs could inspect certain containers and cabinets within the laboratory area would be excluded from inspection. **Exhibit 7**, Defendant's August 26, 2005 correspondence.

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[2] Defendant's counsel suggested that he was not prepared with his client's answer by the 9 am August 29, 2005 deadline because he was under the impression that he was supposed to provide his answer one day earlier, on August 28. First, the August 19 letter states clearly in two places that August 29 was the deadline by which Defendant had to respond. Second, nothing prevented Defendant from contacting Plaintiffs with its decision on August 28. Finally, if Defendant's counsel was unprepared at 9 am on August 29, he would most certainly not have been ready to proceed with his client's answer one day earlier. When pressed on these excuses, Defendant's counsel became belligerent and abusive.

25. The letter also reiterated Defendant's untimely additional condition that the DUSA Plaintiff's must also submit to an entry.

I affirm under penalty of perjury that the foregoing is true and correct.

Valerie Brand Pipano, Esq.

Dated: September 8, 2005
Sworn to and subscribed before me
this 8th day September, 2005.

Notary Public of the Commonwealth of Pennsylvania
My commission expires:

NOTARIAL SEAL
LILY F LEONG, Notary Public
City of Philadelphia, Phila. County
My Commission Expires February 18, 2006

EXHIBIT "1"

MENARD, MURPHY & WALSH LLP
ATTORNEYS AT LAW

DANIEL M. RABINOVITZ
drabinovitz@mmwlaw.com

August 12, 2005

Via Fax (215)-851-1420

William McNichol, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street Philadelphia PA 19103

Dear Mr. McNichol:

Enclosed is New England Compounding Pharmacy's response to DUSA's request for Entry Upon Land (the "Request").

As the enclosed pleading indicates, New England Compounding Pharmacy ("NECP") objects to the Request primarily because the Request is not likely to lead to relevant admissible evidence. (Not to mention patient privacy and HIPPA concerns) Simply put, it is inconceivable that inspecting NECP's premises could lead to a scintilla of relevant evidence relating to any of the prima facie elements of DUSA's Inducement of Infringement claims.

Given this complete lack of relevance, it seems clear that DUSA is merely interested in conducting a fishing expedition to attempt to discover details of NECP's manufacturing plant, in order to arm DUSA's representatives out in the field, so that those representatives can continue to make knowingly false statements about NECP to NECP's potential customers. All of these considerations lead NECP to conclude that at this time they will not permit DUSA to enter upon their premises.

However, I am mindful of the clear admonition Judge Gorton gave both of us at the Scheduling Conference with respect to burdening the court with discovery disputes and the probability that if the parties involve the court in those types of disputes, that the prevailing party is likely to be awarded costs. Therefore, if you wish to discuss this matter further and you are able to be more specific as to what DUSA is really after, and you can articulate a valid reason as to why an inspection might lead to relevant

admissible evidence, I am willing to talk about this with you and under the appropriate circumstances I am willing to speak with my client about reconsidering our position.

Very truly yours,

Daniel M. Rabinovitz

CC: Gregory Conigliaro w/enc.
Mona Patel, Esq. w/enc.

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC. and QUEEN'S UNIVERSITY AT KINGSTON,

Plaintiffs,

v.

NEW ENGLAND COMPOUNDING PHARMACY, INC.,

Defendant.

Civil Action No. 04-12703 NMG

NEW ENGLAND COMPOUNDING PHARMACY INC.'S RESPONSE TO DUSA'S REQUEST FOR ENTRY UPON LAND

Now comes the defendant, plaintiff-in-counterclaim, New England Compounding Pharmacy Inc. ("NECP") and hereby responds to DUSA's request to enter upon NECP'S land for purposes of inspection (the "Request").

NECP objects to the Request on the grounds that the Request is not likely to lead to relevant admissible evidence. Additionally, NECP objects to the Request because of patient privacy issues and HIPPA considerations. At this juncture, DUSA has not articulated any reason why DUSA believes an inspection of NECP's premises could lead to any relevant evidence relating to any of the elements DUSA's claims of Inducement of Infringement.

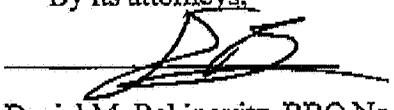
Given this complete lack of relevance, it seems clear that DUSA is merely interested in conducting a fishing expedition to attempt to discover details of NECP's manufacturing plant, in order to arm DUSA's representatives out in the field, so that those representatives can continue to make knowingly false statements about NECP to

NECP's potential customers. All of these considerations lead NECP to conclude that at this time they will not permit DUSA to enter upon their premises.

NECP has offered to discuss the Request with DUSA and while NECP is hopeful that this matter can be resolved without the assistance of the court, NECP reserves its right to raise additional arguments which become relevant as a result of any discussions with counsel for DUSA, in the event DUSA does in fact seek to burden the Court with this issue.

NEW ENGLAND COMPOUNDING PHARMACY, INC.

By its attorneys,



Daniel M. Rabinovitz, BBO No. 558419
Menard, Murphy & Walsh LLP
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Boston, Massachusetts 02109
(617) 832-2500

Dated: August 12, 2005

EXHIBIT "2"

ReedSmith

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Fax 215.851.1420

Valerie Brand Pipano
Direct Phone: 215.851.8289
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August 12, 2005

VIA FACSIMILE AND FIRST CLASS MAIL

Daniel M. Rabinovitz
Menard, Murphy & Walsh LLP
60 State Street - 34th Floor
Boston, Massachusetts 02109

Re: DUSA v. New England Compounding Pharmacy
Civil Action No.: 04-12703-NMG

Dear Mr. Rabinovitz:

This letter is in reply to New England Compounding Pharmacy Inc.'s Response to DUSA's Request for Entry Upon Land, and your August 12 letter suggesting that New England Compounding Pharmacy Inc. ("NECP") might withdraw its objection should DUSA articulate the reason an entry upon land may lead to the discovery of relevant information.

DUSA's entry upon, and inspection of, the NECP premises is necessary to defend against the allegations asserted in NECP's counterclaims. As you are aware, the counterclaims are grounded in the claim that DUSA purportedly made false and/or misleading remarks disparaging the quality and source of NECP's compounds of aminolevulinic acid solution. The physical conditions under which NECP manufactures its ALA product is highly relevant information concerning this counterclaim. Indeed, it is one of the central facts of this case. Thus, the requested entry and inspection is entirely appropriate.

Should NECP elect to withdraw its counterclaims and acknowledge that there is nothing false or misleading about DUSA's statements, DUSA will of course consider withdrawing its request for entry upon land. Absent that, we remain convinced that the Court will find that an inspection is appropriate and will likely lead to the discovery of relevant information.

With respect to the privacy and HIPAA concerns that you secondarily raise, the Request for Entry Upon Land seeks to inspect of NECP's premises and not its documents. The areas that DUSA seeks to inspect are plainly set out in the Request for Entry Upon Land and do not include any area that should lead to disclosure of patient-specific or HIPAA-protected information. Please advise us of any areas within those set out in the Request which you believe might raise privacy issues, and we will be happy to work with you to resolve legitimate concerns. Should valid HIPAA concerns later be implicated by document requests separate from the entry upon land, we are confident that the protective order and appropriate redactions of patient information will prove adequate to protect patient privacy.

ReedSmith

In order to make the appropriate travel plans, please let us know by noon on Monday, August 15, 2005 whether, in light of the foregoing, you intend to allow our entry and inspection on Tuesday. If we do not hear from you by then, you may expect to see a motion filed with the Court.

Very truly yours,

Valerie Pipano

Valerie Brand Pipano

cc: William J. McNichol, Esq.
Maryellen Feehery, Esq.
Edward Naughton, Esq.
Mona Patel, Esq.

EXHIBIT "3"

ReedSmith

Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
215.851.8100
Fax 215.851.1420

Valerie Brand Pipano
Direct Phone: 215.851.8289
Email: vbrand@reedsmith.com

August 15, 2005

VIA FACSIMILE AND FIRST CLASS MAIL

Daniel M. Rabinovitz
Menard, Murphy & Walsh LLP
60 State Street - 34th Floor
Boston, Massachusetts 02109

Re: DUSA v. New England Compounding Pharmacy
Civil Action No.: 04-12703-NMG

Dear Mr. Rabinovitz:

This correspondence follows the voicemail message that I left for you at approximately 12:15 today, and an August 12, 2005 letter in which we provided New England Compounding Pharmacy Inc. ("NECP") with an understanding of the necessity and probative value of the entry upon land. DUSA provided this information in an effort to resolve this discovery dispute without unnecessarily burdening the Court, and based on your August 12 representation that NECP would withdraw its objection should DUSA provide grounds for the entry.

In our letter, we also requested that, in light of the set travel plans of ourselves and our expert, you inform us by noon today whether NECP would withdraw the objection that you served late Friday. Noon has come and gone. We also called you to determine whether you intended to withdraw your objection, and in an effort to comply with our 'meet and confer' obligations pursuant to Federal and Local Rules. We still have not heard from you.

DUSA still hopes to go forward with the entry tomorrow, and requests that you inform us immediately whether NECP intends to withdraw its objection. Regardless, the parties should confer and attempt to resolve this issue today. I can be reached at 215.851.8289.

If you have any questions or comments about the foregoing, do not hesitate to contact me.

Very truly yours,

Valerie Pipano

Valerie Brand Pipano

EXHIBIT "4"

Brand, Valerie N.

From: Brand, Valerie N.
Sent: Monday, August 15, 2005 3:04 PM
To: 'Dan Rabinovitz'
Cc: McNichol, William J., Jr.
Subject: RE: Your letters of today

Okay. I will call you on the 18th at 2. At that time, please have your client's decision regarding whether to withdraw the objection. And, to the extent the entry will go forward without a motion, please have dates for that as well.

Valerie Brand Pipano
vbrand@reedsmith.com
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
215.851.8289
Fax 215.851.1420

From: Dan Rabinovitz [mailto:drabinovitz@mmwlaw.com]
Sent: Monday, August 15, 2005 3:00 PM
To: Brand, Valerie N.
Cc: McNichol, William J., Jr.
Subject: RE: Your letters of today

The 17th will not work, but the 18th will--any time after 2:00 PM.

From: Brand, Valerie N. [mailto:VBrand@ReedSmith.com]
Sent: Monday, August 15, 2005 2:50 PM
To: Dan Rabinovitz
Cc: McNichol, William J., Jr.
Subject: RE: Your letters of today

Mr. Rabinovitz,
As I am sure you can understand, we do not want this issue to remain unresolved indefinitely. Please provide us with your client's answer by Wednesday, August 17. We should also talk on that date, either to have a required 'meet and confer' before a motion is filed, or to set up dates and times for the entry. Let me know what time you are free for a conference call on the 17th.

Valerie

Valerie Brand Pipano
vbrand@reedsmith.com
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
215.851.8289
Fax 215.851.1420

From: Dan Rabinovitz [mailto:drabinovitz@mmwlaw.com]
Sent: Monday, August 15, 2005 2:30 PM
To: Brand, Valerie N.
Subject: Your letters of today

Dear Ms. Brand-Pipano:

I just received your recent letters. I will discuss the points set forth in them with my client as soon as possible. Without waiving any objections, please be advised that in any event it will not be possible for entry to occur tomorrow August 16th and therefore no representative from DUSA should appear at NECP.

Incidentally, please examine the original Request for Entry and notice that the address you requested to enter upon is not NECP's address. (I believe the address listed may in fact be DUSA's address)

When I have had the chance to discuss this matter further with my client, I will contact you. I suggest that you refrain from filing any motions with the court until we can complete our efforts to resolve this matter.

Dan Rabinovitz
Menard, Murphy & Walsh LLP
60 State Street
Boston MA 02109
(617) 832-2500
(617) 832-2550 (Fax)

EXHIBIT "5"

MENARD, MURPHY & WALSH LLP
ATTORNEYS AT LAW

ANITA WYZANSKI ROBBOY
robboy@mmwlaw.com

August 18, 2005

Via Fax (215)-851-1420

Valerie Brand Pipano, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dear Ms. Brand Pipano:

The purpose of this letter is to facilitate our "meet and confer" obligations with respect to the issue of DUSA's request to enter upon NECP's land (the "Request") and is made without waiving any previous objections, or NECP's right to supplement its prior written objections.

At the outset, please understand that NECP's counterclaim does not relate to statements made by DUSA relating to the condition of NECP's physical plant. Rather, NECP's counterclaim relates to false statements made by DUSA relating to the quality of NECP's ALA compounds and false statements relating to the source of the chemical compounds used in NECP's compounding process. If DUSA is truly interested only in facts which relate to these issues, there are more effective, less intrusive and more relevant ways to discover these facts. For example, obtaining samples suitable for laboratory analysis would be the best way for DUSA to conduct discovery relating to the quality of NECP's final product. With respect to the source of the chemicals used by NECP in its ALA compounding process, document requests, and/or deposition testimony would reveal that NECP obtains these compounds from an FDA registered chemical distribution company. Therefore, NECP is not convinced that DUSA has articulated a specific, valid reason for the requested inspection.

In addition, please be advised that the portion of your Request that seeks to examine areas related to the "manufacture, [and] fabrication" of ALA describes processes which NECP does not perform. In other words, NECP does not manufacture or fabricate ALA. Rather, NECP performs compounding services by combining compounds to produce a product in final dosage form.

Despite DUSA's failure to articulate a specific relevant reason for the inspection, in the interest of resolving this dispute without the necessity of troubling the Court, if,

and only if, DUSA agrees to the following conditions, NECP will permit DUSA to inspect the areas described below:

1. The inspection will occur during a time other than NECP's regular business hours, so as to minimize patient privacy and patient safety concerns. We would suggest an inspection beginning at 5:30 P.M. on any of the following dates: September 7, 8, 9, 12 or 13.

2. DUSA's inspection team shall consist of no more than the following individuals: one company representative; one attorney; one photographer and one videographer;

3. The inspection will be limited to NECP's Compounding Laboratory used for compounding ALA (the "Compounding Lab"). This is a single room where NECP's Flowscience Hepafiltration hood is stationed, (containing an electronic analytical balance scale) and NECP's refrigeration system.

4. Within the Compounding Lab, there are various cabinets and containers which do not relate in any way to any issue in this litigation and as such, those cabinets and containers will remain closed.

5. With respect to the storage of documents, due to the manner in which documents are stored, it is impossible to allow DUSA unfettered access into document storage areas without compromising patient privacy and violating HIPAA. However, NECP will allow inspectors to examine all of the documents which relate to the ALA compounding process, which consist of formula worksheets and refrigeration temperature logs.

6. No NECP employees shall be photographed or videotaped.

7. Finally, in order to avoid any confrontation during the inspection process, DUSA must agree that if during the inspection NECP believes DUSA is not complying with the parameters set forth above, NECP may terminate the inspection by informing the DUSA inspection team that the inspection is terminated at which time the entire DUSA inspection team will immediately vacate the premises. In the unlikely event that this occurs, the parties would have the right to seek assistance from the Court.

I look forward to discussing this proposal with you at 2:00 P.M.

Very truly yours,

Daniel M. Rabinovitz

CC: Gregory Conigliaro
Mona Patel Esq.

EXHIBIT "6"

ReedSmith

Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103-7301
215.851.8100
Fax 215.851.1420

Valerie Brand Pipano
Direct Phone: 215.851.8289
Email: vbrand@reedsmith.com

August 19, 2005

VIA FACSIMILE AND FIRST CLASS MAIL

Daniel M. Rabinovitz
Menard, Murphy & Walsh LLP
60 State Street - 34th Floor
Boston, Massachusetts 02109

Re: DUSA v. New England Compounding Pharmacy
Civil Action No.: 04-12703-NMG

Dear Dan:

This letter is in response to your request that I place in writing DUSA's position, as discussed yesterday, regarding the seven conditions you have sought to impose on the entry upon land. You have agreed to have a final answer from your client by Friday, August 26 at 9 am as to whether the entry may go forward without a Court Order under the terms as set forth in the Request for Entry Upon Land as modified by this letter.

A response to each of NECP's seven proposed conditions is set forth below. There are two guiding principals, however, that inform our disagreement with several of your conditions.

First, NECP's counterclaims allege that DUSA made false and/or misleading remarks disparaging the quality and source of NECP's ALA-containing products. These counterclaims make highly relevant a number of facts concerning the materials used to make NECP's ALA-containing products, the manner and conditions under which it is made, as well as the procedural safeguards associated with the storage, labeling, packaging and record keeping system of the ALA-containing product. DUSA's inspection will be related to these points.

If your client finds the nature and extent of this discovery uncomfortable, I reiterate the offer I made in my August 12, 2005 letter. Should NECP withdraw its counterclaims and acknowledge that there is nothing false or misleading about DUSA's statements, DUSA will consider withdrawing its request for entry upon land. Absent that, we are unwilling to artificially limit the scope of discovery.

Second, the conditions you proffer suggest that NECP is under the misimpression that DUSA's request for entry upon land is also a request to inspect documents. This is not the case. DUSA seeks to examine the filing and storage system of various records and documents for the reasons set forth above, if, indeed, NECP has any record storage system. It does not intend to examine the contents of documents

ReedSmith

at the time of entry. The examination of filing and record storage systems will not lead to the disclosure of patient-specific or HIPAA-protected information.

Moreover, as addressed in my August 12 letter, to the extent HIPAA concerns may be later implicated by DUSA's document requests, we are confident that the protective order and appropriate redactions of patient information will prove adequate to protect patient privacy. It should also be noted that the request for entry upon land, or the fact that no inspection of documents will take place at that time, does not constitute a waiver on the part of DUSA and certainly does not obviate NECP's obligation to provide materials responsive to requests for the production of documents.

Now to the specific conditions you proffer:

1. Per your request, DUSA agrees to begin its inspection at 5:30 pm on one of the dates that you proffered. We are still confirming the evening availability of our expert, videographer and photographer, and will let you know as soon as possible which date or dates will work.

2. NECP suggests that the inspection team should consist of no more than one company representative, one attorney, one photographer and one videographer. We cannot agree to this condition. Along with the photographer and videographer, DUSA will require two attorneys (one from the office of lead counsel and one local counsel) and an expert on appropriate and customary practices and procedures for making[1] pharmaceuticals. DUSA is entitled to be represented by its lead counsel, and is also entitled to be represented by local counsel in the event that there is a need to seek assistance from the Court. Expert involvement in areas outside the realm of layman knowledge is also common practice. It should further be noted that our expert's Acknowledge of Protective Order has been served on you, and you did not object within the requisite three days. As a concession to NECP in this regard, DUSA will not bring a company representative to the inspection.

3. For the reasons set forth above, DUSA cannot agree to limit the areas of inspection to the room containing NECP's compounding laboratory.

4. NECP broadly suggests that DUSA may not inspect various cabinets and containers within the compounding laboratory (an area that NECP concedes is relevant) based simply on a representation that NECP does not believe these various cabinets and containers to hold materials related to this litigation. DUSA cannot accept this condition. As our conversation and correspondence make plain, the parties have vastly different ideas about what materials are relevant to the above-captioned claims. You request excluding areas of inspection that are likely to lead to the discovery of admissible evidence relating to the quality and integrity of the ALA-containing products. DUSA is entitled to know, for example, if the cabinets and/or containers hold materials that might cause cross-contamination or are otherwise not permissible in a manufacturing area. To the extent that NECP is concerned that the inspection of these cabinets and containers will reveal commercially sensitive information, we remind you that there is a protective order in place.

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[1] Your August 18, 2005 letter purports to distinguish between words like "manufacture" and "fabricate" and the purported compounding process performed by NECP. In the context of an infringement action, and specifically for the purposes of discovery in the above-captioned matter, it is inappropriate to draw this distinction. These words may and shall be used broadly and interchangeably in the context of this matter, and NECP should construe them as such.

ReedSmith

5. As stated above, DUSA does not intend to examine individual documents in the course of its entry and inspection. Accordingly, the entry upon land will not implicate HIPAA or other privacy concerns.

6. DUSA agrees that it will not purposefully photograph or videotape NECP employees. DUSA does ask, however, that a NECP employee be available to direct DUSA through the facility.

7. DUSA will agree to comply with the terms of entry and inspection as set forth in the Request for Entry Upon Land, and as modified by the terms as set forth herein. Should the parties disagree during the course of entry as to the scope of inspection, DUSA agrees that the parties have the right to terminate the inspection and seek assistance from the Court.

I expect to hear from you by Friday, August 26 at 9 am as to whether or not the entry will go forward under the conditions set forth herein. If you have any questions or comments about the foregoing before then, do not hesitate to contact me.

Also, since you indicated that you will be unavailable for the 30(b)(6) deposition noticed for September 20, please let me know by next Friday alternate dates on which you will be available.

Very truly yours,

Valerie Pipano

Valerie Brand Pipano

cc: William J. McNichol, Esq.
Maryellen Feehery, Esq.
Edward Naughton, Esq.

ReedSmith

bcc: Mona Patel, Esq.
Tamara J. Yorita, Esq.

EXHIBIT "7"

MENARD, MURPHY & WALSH LLP
ATTORNEYS AT LAW

DANIEL M. RABINOVITZ
drabinovitz@mmwlaw.com

August 26, 2005

Via Fax (215)-851-1420

Valerie Brand Pipano, Esq.
Reed Smith LLP
2500 One Liberty Place
1650 Market Street
Philadelphia, PA 19103

Dear Ms. Brand Pipano:

In furtherance of our discussions with respect to the issue of DUSA's request to enter upon NECP's land (the "Request") and without waiving any previous objections, or NECP's right to supplement its prior written objections, there are several key points in your letter of August 19, 2005 which merit a response.

Both your letter of August 19, 2005 and your client's entire position, ignore a simple fact which NECP made DUSA aware of long ago: NECP is not a manufacturer and thus is not regulated by the FDA. NECP is a compounding company, which is regulated by the Massachusetts Board of Registration in Pharmacy. Therefore, not only is your footnote in your August 19, 2005 letter inaccurate, but more importantly your stated reason for requesting the inspection in the first place is completely misguided and demonstrates a total lack of understanding of the compounding industry as a whole.

With respect to the numbered points in your letter of August 19, 2005, here is NECP's revised offer:

1. If the inspection occurs, it will begin at 5:30 p.m. on a mutually agreeable date in the near future.

2. NECP will allow the following individuals into its premises: one lead counsel, one local counsel, one photographer, and one videographer. However, if DUSA insists on bringing an expert in the field of FDA regulations, DUSA must also agree that by NECP assenting to this, NECP has not waived its right to challenge the qualifications of the expert (to testify or provide evidence by way of affidavit) on the grounds that the expert is not qualified to offer an expert opinion on material or relevant subject matter. Contrary to the statement in your August 19th letter, NECP's failure not to object to the Acknowledgement of Protective Order has absolutely no bearing on NECP's right to object to that expert to enter upon its land, nor on NECP's right to object to any evidence offered by the expert. Simply put, as a compounder,

the FDA's regulations and standards are completely irrelevant to any issue in this case.

3. For the reasons set forth above, NECP can not agree to allow the inspection to occur outside of the compounding laboratory.

4. Once again, your stated reasons for wanting to open cabinets in the compounding laboratory completely misunderstands the nature of NECP's business and the nature of the compounding industry as a whole. NECP does not manufacture anything. It receives orders from physicians to fill and ship prescriptions and it does so. Previously, you indicated during a phone call that DUSA was willing to agree not to open the cabinets if NECP certified they contained items wholly unrelated to the litigation. That offer still stands.

5. We are in agreement that the inspection will not encompass the review of documents.

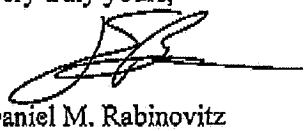
6. NECP will have a representative present to direct the inspection, but DUSA must agree not to photograph any NECP employee, whether "purposefully" or otherwise.

7. We agree that if NECP believes DUSA has violated the terms of our agreement regarding the inspection, upon notification of this belief DUSA will leave the premises immediately.

Finally, since DUSA insists that the nature of our counterclaim has put at issue whether the conditions of NECP's compounding process are inferior to DUSA's manufacturing processes, DUSA must agree to allow NECP inspect its facilities on a mutually convenient date and under the same conditions set forth above.

I look forward to hearing from you soon.

Very truly yours,



Daniel M. Rabinovitz

CC: Gregory Conigliaro
Mona Patel, Esq.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DUSA PHARMACEUTICALS, INC., a New Jersey corporation; and QUEEN'S UNIVERSITY AT KINGSTON, a Canadian academic organization,	:	Civil Action No. 04-12703-NMG
Plaintiffs,	:	
v.	:	[JURY TRIAL DEMANDED]
NEW ENGLAND COMPOUNDING PHARMACY, INC., a Massachusetts corporation,	:	
Defendant.	:	

AFFIDAVIT OF DAVID L. CHESNEY

I, David L. Chesney, upon my oath according to law, hereby depose and state as follows:

1. I am the Vice President, Quality and Compliance Management Services for PAREXEL Consulting (formerly known as KMI, a division of PAREXEL), and have been retained by Plaintiffs in the above-captioned matter to participate and serve as a consulting expert with respect to the inspection of the premises and facility of New England Compounding Pharmacy, Inc. I executed an Acknowledgement of the Stipulated Protective Order on August 8, 2005.

2. Prior to joining PAREXEL Consulting in 1995, I served 23 years with the FDA. Between 1972 and 1988, I advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and

Philadelphia District Offices. In 1991, I was appointed the District Director, San Francisco District Office, where I served until joining KMI in 1995.

3. Since joining PAREXEL Consulting, I have provided compliance consulting services to clients throughout North America, Europe and Japan, and I presently manage two other Vice Presidents and several of PAREXEL Consulting's Principal Consultants. In this capacity, I oversee strategic compliance consulting and FDA regulated business process consulting services to the pharmaceutical, medical device and biotechnology industries, and the Food and Drug legal community.

4. I am the Vice President, Quality and Compliance Management Services for PAREXEL Consulting (formerly known as KMI, a division of PAREXEL), and have been retained by Plaintiffs in the above-captioned matter to participate and serve as a consulting expert with respect to the inspection of the premises and facility of New England Compounding Pharmacy, Inc. I executed an Acknowledgement of the Stipulated Protective Order on August 8, 2005.

5. Prior to joining PAREXEL Consulting in 1995, I served 23 years with the FDA. Between 1972 and 1988, I advanced from Investigator to Supervisory Investigator and Director, Investigations Branch, working in the Boston, Seattle and Philadelphia District Offices. In 1991, I was appointed the District Director, San Francisco District Office, where I served until joining KMI in 1995.

6. Since joining PAREXEL Consulting, I have provided compliance consulting services to clients throughout North America, Europe and Japan, and I presently manage all of PAREXEL Consulting's Principal Consultants. In this capacity, I

oversee strategic compliance consulting and FDA regulated business process consulting services to the pharmaceutical, medical device and biotechnology industries, and the Food and Drug legal community.

7. I maintain broad experience in good manufacturing practice ("GMP") and good clinical practice ("GCP") compliance, including both manufacturing and clinical investigation compliance areas; development of corporate regulatory compliance strategy; auditing and/or development of management controls for regulatory compliance; analysis and development of quality assurance organizations and quality systems; laboratory controls; failure and deviation investigations; investigation and resolution of data integrity issues; management of responses to regulatory inspections and enforcement actions; and have provided training in compliance topics.

8. I understand that the safety, quality, purity, potency and efficacy of the ALA-containing product compounded and sold by the New England Compounding Pharmacy, Inc. has been put at issue in this case by certain counterclaims asserted by the Defendant.

9. It is also my understanding that, as a compounding pharmacy, Defendant has not been subjected to inspection by the Food and Drug Administration ("FDA"), and that therefore the FDA has made no determination as to the adequacy of Defendant's manufacturing practices or the safety, identity, strength, quality and purity characteristics of its ALA-containing product.

10. It is my opinion, based on my knowledge and experience in the field, that the safety, identity, strength, quality and purity characteristics, of a drug can

not be assured without an examination of the methods used in, and the facilities and the controls used for, its manufacture, processing, packing and/or storage (in this case by a compounding pharmacy).

11. An examination of these practices and conditions is indeed crucial to determining the safety, identity, strength, quality and purity characteristics of a drug product. The strict control of manufacturing processes, procedures and conditions are routinely relied upon as means of assuring the safety, identity, strength, quality and purity characteristics of drug products. Indeed, these are the best available means to insure that a product conforms to the standards that patients, physicians and hospitals expect of a drug sold in this country. The reason for this is that finished product testing alone cannot provide adequate assurance of uniform quality throughout a manufactured batch of drug product.

12. Because the risk of inadvertent contamination of a drug product , or the existence of factors that may contribute to the failure of a drug product to meet its specifications and acceptance criteria may occur prior to, during or after the manufacturing process, an assessment should properly include an inspection of areas related to the receipt, sampling and testing of raw materials, containers, closures, packaging and labeling materials; the use and maintenance of equipment and utilities (water systems, lighting, heating/ventilating/dust control systems, and the like); and the creation and use of pertinent records, files, papers and other materials generated in connection with manufacturing, packaging, testing and distribution of the drug product.

13. I understand that Defendant has objected to the inspection of certain containers and cabinets within its compounding facility. It is important to inspect all areas within the facility to ensure that the facility itself is properly designed and constructed so as to preclude contamination and facilitate cleaning; that it has adequate lighting, ventilation and environmental controls; and that there is adequate space for the operations conducted therein relative to the manufacturing of products produced in the facility. Also, it is important to determine whether there is any aspect of the design or construction of the facility, the areas where the product is made (and/or any other relevant areas such as raw material receiving areas and finished product storage areas) that might cause contamination or otherwise adulterate the ALA-containing product or components thereof.

I affirm under penalty of perjury that the foregoing is true and correct.

David L. Chesney

David L. Chesney

Dated: September 7, 2005
Sworn to and subscribed before me
this 7th day September, 2005.

Notary Public of the Commonwealth of
Massachusetts
My commission expires: October 27, 2006